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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,548	05/29/2001	Gunnar Grue-Sorensen	P 277978	2538

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EXAMINER

BADIO, BARBARA P

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,548

Applicant(s)

GRUE-SORENSEN ET AL.

Examiner

Barbara P. Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8,10-15 and 21-42 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8,10-15 and 21-23 is/are rejected.
- 7) ☒ Claim(s) 24-42 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

First Office Action on the Merits of a RCE

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 13, 2005 has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of the Application

3. Claims 1-6, 8, 10-15 and 21-42 are pending in the present application.

Claim Rejections - 35 USC § 112

4. The rejection of claims 24-42 under 35 USC 112, first paragraph is withdrawn.
5. The rejection of claims 1-6, 8, 10-15 and 21-23 are rejected under 35 USC 112, first paragraph is maintained.

Applicant argues the amendment to the instant claims overcomes the rejection. Applicant's argument was considered but not persuasive for the following reasons.

First, it is noted that no amendment was made to claims 21, 26 and 29 and, thus, the rejection stands for the reasons given in previous Office Actions.

In regards to claims 1-6, 8, 10-15, 22 and 23, the phrase "with the exclusion of hyperparathyroidism" does not find support in the present specification. The present specification does not disclose hyperparathyroidism as a "related bone condition" and, thus, cannot provide support for its exclusion from the claimed invention (see MPEP § 706.03(o)). Therefore, the instant claims stand rejected as containing subject matter not described in the specification as to convey to the skilled artisan that applicant, at the time the application was filed, had possession of the claimed invention.

The instant claims also recite the phrase "related bone conditions". However, the present specification fails to provide descriptive information of what is meant and, thus, encompassed by the phrase "related bone conditions". Adequate written description requires more than the recitation of said phrase in the present specification.

For these reasons and those given in previous Office Actions, the rejection of claims 1-6, 8, 10-15 and 21-23 are rejected under 35 USC 112, first paragraph is maintained.

Note: Applicant did not point to where support for the present amendment can be found and the examiner was unable to find support for said amendment.

6. Claim 21 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment, does not reasonably provide enablement for prophylaxis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are (1) the nature of the invention, (2) the breadth of the claims, (3) the state of the prior art, (4) the predictability or unpredictability of the art, (5) the amount of guidance or direction presented, (6) the presence or absence of working examples, (7) the relative skill in the art and (8) the quantity of experimentation necessary. When the above factors are taken into consideration, the examiner's position is that one skilled in the art could not perform the invention commensurate in scope with the instant claim without undue experimentation.

Claim 21 recites a method for the "treatment and **prophylaxis**" of osteoporosis and related bone conditions utilizing the claimed compounds. Webster defines "prophylaxis" as the protective treatment for or prevention of disease. The art teaches treatment regimens for osteoporosis as recited by the instant claims. However, (a) the art does not teach prevention of said disease and (b) there is no known method(s) for the determination of a person susceptible to osteoporosis and, thus, in need of preventive treatment. The present specification lacks guidance and/or working

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examples of prevention of osteoporosis as encompassed by the instant claim.

Therefore, in order to practice the claimed invention, the skilled artisan would have to first search the prior art to find, if possible, a model for determination of a person prone to osteoporosis and, thus, in need of preventive treatment. The amount of experimentation necessary to make said determination is undue because of the lack of guidance and/or working examples in the present specification.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-6, 8, 10-15 and 21-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims recite the treatment of osteoporosis and "related bone conditions" utilizing the claimed compounds. However, it is unclear what is meant and, thus, encompassed by the phrase "related bone conditions". Therefore, the metes and bound of the claimed invention is indefinite.

Claim Objections

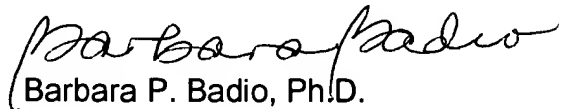
9. Claims 24-42 are objected to as being dependent upon a rejected base claim.

Telephone Inquiry

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1617

BB
July 22, 2005